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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/512,090

02/11/2005

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

01/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/512,090	Applicant(s) LEE ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10-14,17 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-8,10-14,17,20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 10/07/2008 have been entered. Any rejection/objection from the previous office action filed 07/07/2008 not addressed in the action below has been withdrawn.

Claim Objections

Claim 17 objected to because of the following informalities: claim 17 should read as currently amended since it now depends upon new claim 25, previously it depended upon claim 16.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8,10-14,17,20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically independent claims 7 and 25 from which all the other claims are dependent upon now state by amendment that the mixture of protein and sulfated polysaccharide are prepared at **room temperature**, the examiner could not find support for this new limitation within the specification.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-8,10-12,14,17,20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (WO 01/28524 A1), for the reasons set forth in the previous office action filed 07/07/2008. A new rejection over new claims 20-25 were necessitated by applicant's amendments to the claims.

Regarding new claims 20-24 as described in previous office actions Scott teaches sustained release microspheres and the method to produce them, the microspheres are comprised of a macromolecule (including therapeutic proteins), a water soluble polymer (including PEG and starch, defined by applicants as protein stabilizer), and a complexing agent (including sulfated dextran, heparin and chondroitin), the microparticle could further be coated by compounds such as fatty acids and lipids (same as claimed hydrophobic material). See pag 1 lin 1-pag 15 lin 21, pag 19 lin 26-pag 26 lin 15, pag 28 lin 6-pag 30 lin 4 and claims 1-3,8-9 and 16-23. Thus the Scott reference anticipates applicants claimed solid formation. Regarding claim 25 Scott teaches that the water soluble polymer (same as claimed protein stabilizer) is added with the protein and complexing agent.

Response to Arguments

The examiner has removed the previous rejections under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (WO 01/28524 A1) in view of Straub et al. (US 6,932,983 B1) and as being unpatentable over Edwards et al. (US 5,985,309) in view of Straub et al. (US 6,932,983 B1). While the examiner does not find applicants arguments persuasive these rejections have been removed since they are now redundant as applicants have removed the previous limitation of the use of a non-aqueous solution in step (b) of claim 7.

Applicant's arguments filed 10/07/2008 have been fully considered but they are not persuasive.

Applicants assert that Scott does not teach the claimed processes to prepare the solid formation following steps a)-c) in particular the reference is silent on preparing the mixture of step a) at room temperature.

As noted above the examiner believes the new limitation that the mixture is prepared at room temperature is new matter. Regardless it is noted by the examiner that the step of heating the mixture described within Scott is clearly optional, note that claim 19 states the microspheres are stabilized by a crosslinking agent **and/or** exposing the microsphere to an energy source, **preferably heat**. Furthermore at page 16 lines 19-20 Scott states the microspheres **optionally** are contacted with a crosslinking agent and/or an energy source under conditions sufficient to stabilize the particle. Lastly since applicants step a) only includes mixing a protein and sulfated polysaccharide at room temperature, the claim does not actually preclude that heat could be applied in an

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additional step after the step of mixing the protein and sulfated polysaccharide.

Regarding applicants assertion that Scott does not teach the claimed process following steps a)-c), clearly Scott states the protein carrier and complexing agent are mixed, meeting step a, the particles formed can then be immersed in an solubilized coating that includes fatty acids or lipids, meeting step b) and lastly the reference describes several techniques for drying the particles (solvent removal) thus meeting step c).

Claims 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub et al. (US 6,932,983 B1). This new rejection was necessitated by applicant's amendments to the claims.

Straub is disclosed in previous office actions and teaches porous drug matrices and the methods of manufacturing, preferably the matrix is in the form of a microparticle. The matrix could incorporate numerous drugs including therapeutically useful proteins which themselves could be encapsulated by a pegylated phospholipid. See abstract, col 2 lin 66-67. The matrix itself was comprised of excipients (preferably in amounts less than 80%) including hydrophilic polymers such as dextran sulfate, sugars (including preferably mannitol and lactose, which as defined by applicants are protein stabilizers) and wetting agents which included stearic acid, wax and sorbitan fatty acid esters such as TWEEN (meeting applicant's claimed hydrophobic material).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7-8,10-14,17,20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (WO 01/28524 A1), for the reasons set forth in the previous office action filed 07/07/2008

As in their arguments above applicants assert that Scott does not disclose their claimed steps a)-c) for producing the solid formation, in particular preparing step a) at room temperature. Applicants further assert there is nothing within Scott that would have led to the use of spray drying as asserted by the office.

The response by the examiner above is incorporated herein, that is Scott discloses that the step of heating is optional and heating after step a) would not even be precluded by the currently amended claims. Regarding applicant's arguments over spray drying, as disclosed within the background of Scott many techniques are routinely used to make microparticles from synthetic and natural polymers including spray drying. Thus it would have been prima facie obvious to the skilled artisan that spray drying could be used to dry the microparticles of the Scott invention. From the disclosure within the background information spray drying was an already well-known and routine technique to dry particles and one of ordinary skill in the art would have a very high expectation of success in using this well known technique to produce the dried particles.

Claims 7-8,11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,985,309) , for the reasons set forth in the previous office action filed 07/07/2008.

Applicant's arguments filed 10/07/2008 have been fully considered but they are not persuasive.

Applicants assert that Edwards does not teach the combination of the recited steps as claimed and does not teach a complex of proteins and sulfated polysaccharides which are encapsulated within a matrix of hydrophobic material.

The examiner respectfully disagrees with applicants assertions above. Clearly Edwards states that the therapeutic agent which can be in combination with a charged complex forming material such as dextran sulfate is added to an aqueous surface active phase that contains a surface active ingredient which includes phospholipids and fatty acids (same as claimed hydrophobic material). See col 8 lin 40. Regarding applicant's assertion that Edwards does not describe a complex of proteins and sulfated polysaccharides encapsulated within a hydrophobic matrix, the examiner notes that such a limitation is not present within the process claims 7 and 25.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618